

REMARKS

Claim 12 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons noted in the official action. The rejected claims are accordingly amended, by the above claim amendments to address and overcome the stated grounds for rejection. In particular, claim 12 is amended to recite that "all of the exhalation gas received by the exhalation manifold is exhausted solely via the exhalation gas exit, thereby eliminating the conflict identified by the Examiner.

It is therefore the Applicant's belief that the presently pending claims now particularly point out and distinctly claim the subject matter regarded as the invention, thereby overcoming all of the raised § 112, second paragraph, rejections. The entered claim amendments are directed solely at overcoming the raised indefiniteness rejection, are not directed at distinguishing the present invention from the art of record in this case, do not add any new matter and do not alter or extend the subject matter or scope of the invention or claims.

Claims 6-12 are then rejected, under 35 U.S.C. § 103(a), as being unpatentable over *Bowe et al.* '656 in view of *Derrick* '491. The Applicant acknowledges and respectfully traverses the raised obviousness rejection in view of the following remarks.

First considering the present invention as recited in amended independent claims 6, 10 and 12, the present invention is directed to a method of manufacturing a nasal cannula that includes a hollow body with a treating gas entrance and an exhalation gas exit at opposed ends of the hollow body and wherein the hollow body is separated into a separate inhalation and exhalation manifolds with the treating gas entrance communicating with the inhalation manifold and the exhalation gas exit communicating with the exhalation manifold. The nasal cannula includes a first fixed length hollow nasal prong that is integral with the hollow body and that communicates with the inhalation manifold to define a treating gas insufflating passage extending between the treating gas entrance and a treating gas exit such that all of the treating

gas supplied to the treating gas entrance is exhausted solely via the treating gas exit. The cannula further includes a second fixed length hollow nasal prong that is integral with the hollow body so that the second fixed length hollow nasal prong communicates with said exhalation manifold to define an exhalation gas sampling passage extending between an exhalation gas entrance and the exhalation gas exit.

According to the present invention as recited in amended claims 6, 10 and 12, the second fixed length hollow nasal prong includes at least one lateral opening that is positioned between the exhalation gas entrance and the exhalation gas exit at a fixed location along the fixed length nasal prong so as to be spaced from soft mucosal tissue of a corresponding nasal passage wherein, during use, the fixed location of the at least one lateral opening spaced from soft mucosal tissue of a corresponding nasal passage. In addition, the at least one lateral opening is large enough to prevent sufficient suction from developing at the exhalation gas entrance to occlude the exhalation gas entrance, and small enough to prevent dilution of an exhaled gas sample by ambient air or excess insufflation gas.

As described in the specification of the present Application, the location and size of the at least one lateral opening are selected and fixed, as recited in claims 6, 10 and 12, so the at least one lateral opening prevent suctional adherence of the second nasal prong to the soft mucosal tissue of the patient's nasal passage and a resulting blockage of the second nasal prong suction. As described in the present Application, the at least one lateral opening prevents suctional adherence of the second nasal prong to the mucosal tissue by providing an alternate air passage that is large enough to relieve any suction that may occur while also avoiding excessive dilution of the exhaled gases.

This also requires that, as described on pages 5 and 6 of the specification and as shown in, for example, Figs. 2 and 4, that the at least one lateral passage be located along the second nasal prong so that the at least one lateral passage cannot itself come into contact with the soft

mucosal tissue of the nasal passage. For this reason, the at least one lateral opening is at a fixed location that is spaced from the soft mucosal tissue of the nasal passage so that the at least one lateral opening cannot come into contact with the soft mucosal tissue.

Turning now to the cited prior art of Bowe `656, this reference relates to a method and apparatus for inhalation of treating gas and sampling of exhaled gas for quantitative analysis. The apparatus includes a cannula body 10 separated into an inhalation manifold 20 and an exhalation manifold 22 by an internal partition 18 and each of the inhalation and exhalation manifolds 20, 22 has a cannula 14 and 16, respectively, that are inserted into the nasal passages. Bowe `656 therefore describes only a common configuration for a nasal cannula, that is, as having separate inhalation and exhalation manifolds with corresponding separate passages into the nasal passages, and does not describe or suggest any of the unique features of the present invention, such as the lateral suction prevention opening or openings located in the second nasal prong.

Derrick `491 concerns an apparatus and method for the delivery of inhalant gas and the exhaustion and collection of respired gas for analysis. The apparatus includes a cannula body member 88 separated into an inhalant gas manifold connected to an inhalant gas cannula 92 and a respired gas manifold connected to an respired gas cannula 94 wherein the inhalant gas manifold includes inhalant gas ports 96 for the delivery of inhalant gas into a space between the patient's nose and mouth. Cannula 92 and 94 each include an upper tubular member, respectively 104 and 106, each of which is telescopically and slidably connected into the corresponding one of cannula 92 and 94 and extends by a variable and adjustable distance into the corresponding nasal passage of the patient. Tubular members 104 and 106 each include a top end opening through which, respectively, inhalant gas from the inhalant gas manifold is delivered into one nasal passage and respired gas collected and provided to the respired gas manifold, with the location of the top end openings in the nasal passages being determined by

the distance that the tubular members 104, 106 are telescoped into or out of the corresponding cannula 92 and 94.

Each of tubular members 104 and 106 further include one or more gas ports 108, 110 that connect with the respective nasal passages, effectively in parallel with the top end openings, to *maximize* the inhalant gas flow from the inhalant gas manifold and the respired gas flow to the respired gas manifold by providing larger total flow path openings between the nasal passages and the respective cannula 92 and 94. That is, and because the intended purpose of gas ports 108, 110 is to *increase the size of the gas flow passage* between the patient's nasal passages and the inhalant and respired gas manifolds, gas ports 108, 110 must be located well within the patient's nasal passages and, in general, in close proximity to the top end openings of tubular members 104 and 106. Gas ports 108, 110 are therefore located in tubular members 104, 106 and in proximity to the top end openings of the telescoping tubular members 104, 106, so that the locations of gas ports 108, 110 in the nasal passages, like the top end openings, will be determined by the distance that tubular members 104, 106 are telescoped into or out of cannula 92 and 94.

It is therefore apparent that there are a number of fundamental distinctions between the present invention as recited in claims 6, 10 and 12 and the teachings of Derrick `491. For example, the purpose of the lateral opening or openings of the present invention is to prevent or relieve suctional adhesion formed between the second nasal prong and the soft mucosal tissue of the nasal passage. This requires that the lateral opening or openings be large enough to relieve suction, but not so large as to dilute the exhaled gases to an undesirable extent. In contrast, the purpose of gas ports 108, 110 of Derrick `491 are to increase the size of the flow path between the nasal passages and the tubular members 104, 106 and thus between the nasal passages and the inhalent and respired gas manifolds. This, in turn, requires that gas ports 108, 110 be of a size on the same order as the tip openings of tubular members 104, 106,

which would result substantial dilution of the exhaled gases if gas ports 108, 110 were exposed to the outside air. The purpose of gas ports 108, 110, however, that is, to increase the size of the flow passages between the nasal passages and the manifolds, requires that gas ports 108, 110 be located well within the nasal passages, at approximately the locations of the tip end openings. While this prevents the dilution of the exhaled gas by outside air, it also means that gas ports 108, 110, like the tip end passages, are located within the nasal passages and therefore within close proximity to the soft mucosal tissues of the nasal passages, so that gas ports 108, 110 are subject to the same risk of clogging and suctional adherence to the soft mucosal tissues at the tip end openings. This also requires that the locations of gas ports 108, 110 be variable, like those of the tip end openings, which is why gas ports 108, 110 are located on telescoping tubular members 104, 106 rather than being at fixed locations with respect to the manifolds.

It is therefore apparent that gas ports 108, 110 of Derrick '491 and the associated structures are completely and fundamentally different and distinct from the structures of the present invention. For example, and in complete contrast to Derrick '491, the lateral opening or openings of the present invention are located in the nasal prongs, and not within telescoping, variable length tubular member extensions of the nasal prongs.

In further contrast, the lateral opening or openings of the present invention are spaced apart from the soft mucosal tissues of the nasal passage while the gas ports of Derrick '491 are located within the nasal passages and thus in close proximity to the soft mucosal tissues.

In still further contrast, the lateral opening or openings of the present invention are at fixed locations relative to the manifolds, so that the lateral opening or openings cannot come into contact with the soft mucosal tissue of the nasal passages while the gas ports of Derrick '491 are at variable distances from the manifolds.

In yet further contrast, the lateral opening or openings of the present invention are of a size large enough to relieve suction between the nasal prong and the mucosal tissue, but not so large as to dilute the exhaled gases to an undesirable extent while the gas ports of Derrick `491 are of a size on the order of the tip end openings because the intent of the gas ports is to increase the size of the flow paths between the nasal passages and the manifolds.

It is therefore the belief and position of the Applicant that for the reasons discussed above Derrick `491 does not teach, suggest or show the aspects of the present invention discussed above and recited in claims 6, 10 and 12 as amended herein above under the requirements and provisions of either of 35 U.S.C. 103 or 35 U.S.C. 102. The Applicant therefore respectfully requests that the Examiner reconsider and withdraw all rejections of claims 6, 10 and 12 over Derrick `491 under 35 U.S.C. 103 and/or 35 U.S.C. 102, and allow claims 6, 10 and 12 as amended herein above.

It is further the belief and position of the Applicant that because claims 7, 8, 9 and 11 depend from claims 6, 10 and 12 and thereby incorporate all recitations of claims 6, 10 and 12 by dependency, claims 7, 8, 9 and 11 are fully and patentably distinguished over and from Derrick `491 under the requirements and provisions of both 35 U.S.C. 103 and 35 U.S.C. 102 for the reasons discussed above. The Applicant therefore respectfully requests that the Examiner reconsider and withdraw all rejections of claims 7, 8, 9 and 11 over Derrick `491 under 35 U.S.C. 103 and/or 35 U.S.C. 102, and allow claims 7, 8, 9 and 11.

In like manner, and as discussed above, Bowe `656 does not show or suggest the aspects of the present invention discussed above and recited in claims 6, 10 and 12 as amended herein above under the requirements and provisions of 35 U.S.C. 103 and/or 35 U.S.C. 102. For this reason, therefore, that is, because neither Bowe `656 nor Derrick `491 teaches, describes or suggests the above discussed aspects of the present invention.

It is therefore the belief and position of the Applicant that for the reasons discussed above the combination of Bowe `656 in view of Derrick `491 does not teach, suggest or show the aspects of the present invention discussed above and recited in claims 6, 10 and 12 as amended herein above under the requirements and provisions of 35 U.S.C. 103 and/or 35 U.S.C. 102. The Applicant therefore respectfully requests that the Examiner reconsider and withdraw all rejections of claims in view of Bowe `656 and Derrick `491.

If any further amendment to this application is believed necessary to advance prosecution and place this case in allowable form, the Examiner is courteously solicited to contact the undersigned representative of the Applicant to discuss the same.

In view of the above amendments and remarks, it is respectfully submitted that all of the raised rejection(s) should be withdrawn at this time. If the Examiner disagrees with the Applicant's view concerning the withdrawal of the outstanding rejection(s) or applicability of the Bowe et al. `656 and/or Derrick `491 references, the Applicant respectfully requests the Examiner to indicate the specific passage or passages, or the drawing or drawings, which contain the necessary teaching, suggestion and/or disclosure required by case law. As such teaching, suggestion and/or disclosure is not present in the applied references, the raised rejection should be withdrawn at this time. Alternatively, if the Examiner is relying on his/her expertise in this field, the Applicant respectfully requests the Examiner to enter an affidavit substantiating the Examiner's position so that suitable contradictory evidence can be entered in this case by the Applicant.

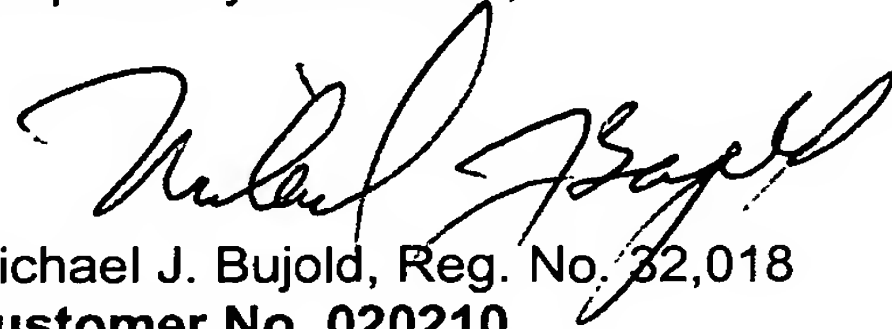
In view of the foregoing, it is respectfully submitted that the raised rejection(s) should be withdrawn and this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time.

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The Applicant respectfully requests that any outstanding objection(s) or requirement(s), as to the form of this application, be held in abeyance until allowable subject matter is indicated for this case.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael J. Bujold", is written over the typed name and contact information.

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